UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/580,144 | 05/18/2006 | Jeremy Cannon | 2099.00041 | 9242 |
| Kenneth I Kohn Kohn and Associates 30500 Northwestern Hwy Suite 410 | | | EXAMINER | |
| | | | TANNER, JOCELIN C | |
| | | | ART UNIT | PAPER NUMBER |
| Farmington Hills, MI 48334 | | | 3731 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 05/11/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|-----------------------|--|--|--|--|
| Office Action Commons | 10/580,144 | CANNON ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | JOCELIN C. TANNER | 3731 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>21 De</u> | ecember 2009 | | | | | |
| | | | | | | |
| <i>,</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| closed in accordance with the practice under L. | parte Quayle, 1955 C.D. 11, 40 | 0.0.210. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1,3-20 and 22-30</u> is/are pending in the | 4)⊠ Claim(s) <u>1,3-20 and 22-30</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdraw | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1, 3-20 and 22-30</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| • • • • | - · <u> </u> | | | | | |
| o) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Preferences Oited (170-032) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | te | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date 6) Uther: | | | | | | |

Art Unit: 3731

DETAILED ACTION

This Office Action is in response to the Amendment filed 21 December 2009. Claims 1, 3-20 and 22-30 are currently pending. The Examiner acknowledges the amendments to claims 1, 17 and 27 and the cancellation of claims 2 and 21.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 December 2009 has been entered.

Claim Objections

2. Claim 1 is objected to because of the following informalities: In line 7, "only into to said instrument" should be "only into said instrument". Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 17 recites the limitation "the trocar" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 3731

6. Regarding claim 20, the recitation "flowing step is further defined as flowing an inert fluid through a neck portion of the trocar proximate to the seal to and out of an opposite distal end thereby removing any substances from the neck portion". It is unclear if the claim is referring to the removal of the substances from the neck portion after the fluid has been delivered to the distal portion of the trocar and up the instrument lumen or the fluid is being removed from the neck portion by delivering the fluid within the downflow lumen. The "opposite distal end" wording is confusing and it is unclear if it is referring to the proximal end or the opposite end of the proximal portion of the trocar which would be the distal end. For the purposes of art rejections, the claim will be interpreted as flowing the fluid back through a neck portion to remove the fluid from the apparatus.

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 1, 3, 5-10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and further in view of Jacobsen et al. (US Patent No. 4,180,068).
- 2. Regarding claims **1, 3 and 6**, Yoon discloses a trocar (10) having an proximal insert end with a housing or "chamber" (14) wherein a pair of universal seals (16a, 16b)

are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument (column 2, lines 37-40, column 4, lines 1-10, column 7, lines 19-22, Fig.2). However, Yoon fails to explicitly disclose perpendicular diaphragms.

Riza et al. teaches a trocar assembly through which a source of inert gas may flow into the abdominal cavity, the trocar including two deformable diaphragms having slits that are perpendicular with respect to other (column 7, lines 53-56, column 8, lines 5-15).

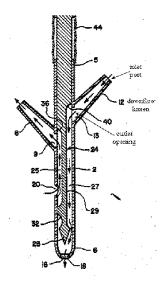
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided consecutive diaphragms having perpendicular slits to enhance sealing structure (column 7, lines 55-57).

However, the combination of Yoon and Riza et al. fails to disclose a downflow lumen having an outlet opening into an instrument lumen and an inlet port opposite thereto.

Jacobsen et al. teaches a trocar including lumens disposed therein for irrigation of fluid through a downflow lumen (12), a lumen in which the instrument is disposed (25, 27), an inlet port that is opposite to an outlet opening (13) that opens only into the instrument lumen (column 3, lines 60-64, Figs. 1, 2). The branch of the trocar being a downflow lumen wherein fluid enters the inlet port and exits through the outlet opening into the instrument lumen in which an instrument is disposed.

Application/Control Number: 10/580,144

Art Unit: 3731



Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Yoon and Riza et al. with a downflow lumen, as taught by Jacobsen et al., to simultaneously introduce and remove fluids from the body of a patient (column 2, lines 1-6).

- 3. Regarding claim **5**, Yoon discloses deformable diaphragms (16a, 16b) having at least one slit (column 6, lines 60-62) through which an instrument is inserted.
- 4. Regarding claims **7 and 8**, Jacobsen et al. teaches a trocar catheter including a neck portion for allowing and insertion of an instrument (24) therethrough, a downflow lumen having a substance removing means through which fluid is removed from about the neck portion of the instrument, the downflow lumen (12) that flows fluid from the proximal end to the opposite end of the instrument lumen (column 4, lines 25-28, Fig. 1).
- 5. Regarding claims **9 and 10**, Jacobsen et al. teaches a downflow lumen extending through at least part of a length of the neck portion, the downflow lumen having a port (13) opening into the instrument lumen, the port being integral with and proximate to the

opposite end or distal end of the instrument lumen, the port used for releasing fluid which flows through the instrument lumen with any substance displaced therein (Fig. 1).

- 6. Regarding claims **14 and 15**, Yoon discloses a trocar (10) formed of plastic, metal or flexible and elastic materials, i.e. rubber (column 4, lines 18-20, 46-47).
- 7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and further in view of Jacobsen et al. (US Patent No. 4,180,068), as applied to claim 3 above, and further in view of Vincent et al. (US Patent No. 5,658,298).
- 8. Regarding claim **4**, Yoon discloses an instrument inserted through resiliently engaging deformable diaphragms (16a, 16b) situated at each end of the chamber (column 3, lines 5-16) but fails to disclose an O-ring.

Vincent et al. teaches and O-ring (71) encircling the distal end of the inner shaft within a trocar cannula (column 4, lines 32-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an O-ring to the trocar of Yoon, as taught by Vincent et al., as an additional safeguard for preventing deflation of the cavity during use (column 4, lines 32-36).

9. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and further in view of Jacobsen et al. (US Patent No. 4,180,068), as applied to claim 1 above, and further in view of Kellogg (US Patent No. 5,968,060).

10. Regarding claim **11**, the combination of Yoon, Riza et al. and Jacobsen et al. discloses all of the limitations previously discussed except for agitating means that are operatively connected to a trocar.

Kellogg teaches an ultrasonic trocar (10) including a handpiece assembly (50), generator (30), braking mechanism (130) and an acoustic assembly (80) through which ultrasonic energy propagates to cause vibration within the acoustic assembly (column 3, lines 17-20, column 11, lines 9-16, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the trocar of the combination of Yoon, Riza et al. and Jacobsen et al. with vibrating means, as taught by Kellogg, to create a penetration opening (column 20-30).

- 11. Regarding claim **12**, Kellogg discloses an automatic transmission component or agitator wherein the transducer assembly is adapted to vibrate at an ultrasonic frequency in response to electrical energy (column 2, lines 9-15).
- 12. Regarding claim **13**, Kellogg teaches an automatic agitator that is an ultrasonic agitator (column 3, lines 16-20).
- 13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and further in view of Jacobsen et al. (US Patent No. 4,180,068), as applied to claim 15 above, and further in view of Banik et al. (US Patent No. 5,256,149).
- 14. Regarding claim **16**, the combination of Yoon, Riza et al. and Jacobsen et al. discloses a trocar (10) formed of plastic or flexible and elastic materials, i.e. rubber

Application/Control Number: 10/580,144

Art Unit: 3731

(column 4, lines 18-20, 46-47, Yoon). The combination of Yoon, Riza et al. and Jacobsen et al. fails to disclose the plastic being transparent.

Banik et al. discloses a trocar (10) constructed entirely of transparent material (column 11, lines 34-38).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the plastic trocar of the combination of Yoon, Riza et al. and Jacobsen et al. to be transparent, as taught by Banik et al., for the predictable result of exteriorly viewing the interior of a trocar during surgical techniques.

- 15. Claims 17, 20 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and further in view of Muschler (US PGPub No. 2004/0191897A1).
- 16. Regarding claims **17 and 27-29**, Yoon discloses the method of maintaining a fluid and airtight environment when introducing a surgical instrument into a patient including the steps of having a trocar (10) having a housing (14) wherein a pair of universal seal (16a, 16b) are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument and inserting an instrument therein such that the seal engage the instrument to form a seal therewith (column 2, lines 37-40, column 3, lines 1-17, column 4, lines 1-10, column 7, lines 19-22, Fig.2). However, Yoon fails to explicitly disclose perpendicular diaphragms.

Riza et al. teaches a trocar assembly through which inert gas is introduced into an abdominal cavity to expand the abdomen, the trocar assembly including two

deformable diaphragms having slits that are perpendicular with respect to other (column 5, lines 35-37, 49-65, column 7, lines 53-56, column 8, lines 5-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided consecutive diaphragms having perpendicular slits to enhance sealing structure (column 7, lines 55-57).

However, the combination of Yoon and Riza et al. fails to disclose flowing an inert fluid through a downflow lumen in the trocar, flowing the fluid through an outlet port of the downflow lumen, into an instrument lumen and up through the instrument lumen, thereby removing any substances in the instrument lumen and preventing the substances from entering the patient.

Muschler teaches an apparatus including a cannula or "trocar" (60), the trocar having irrigation means that control the delivery of saline or an "inert fluid" [0073] to the distal end of the apparatus, a downflow lumen (520) through which the inert fluid flows through an outlet port (524) of the downflow lumen, into and up through the instrument lumen (76) by aspiration means which removes any substances in the instrument lumen and prevents the substances from entering the patient ([0095-0100], Fig. 12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Yoon and Riza et al. with a downflow lumen that delivers fluid into an instrument lumen, as taught by Muschler, to assist in washing debris into the opening and into the instrument passage [0100].

Art Unit: 3731

17. Regarding claim **20**, Muschler teaches the aspiration of the fluid into a collection reservoir, thus removing the fluid from the neck portion of the trocar (Fig. 12).

- 18. Regarding claim **22**, Yoon discloses the method step of puncturing the abdominal wall and inserting the trocar (10) through the incision (column 9, lines 4-8).
- 19. Regarding claim **23**, Yoon discloses the method step of creating an incision using a needle or "obturator" (column 9, lines 4-8).
- 20. Regarding claim **24**, Riza et al. teaches the method step of creating an incision using a stylet or "scalpel" (column 3, lines 59-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a stylet to create an incision using the trocar of Yoon, as taught by Riza et al., since it was well known in the art to make an incision using a scalpel.
- 21. Regarding claims **25 and 26**, Yoon discloses the method of stabilizing the trocar in the incision by engaging the endcap (54) of the chamber (Fig. 2).
- 22. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and in view of Muschler (US PGPub No. 2004/0191897A1), as applied to claim 17 above, and further in view of Vincent et al. (US Patent No. 5,658,298).
- 23. Regarding claims **18 and 19**, Yoon discloses an instrument inserted through a series of resiliently engaging deformable diaphragms (16a, 16b) situated at each end of the chamber (column 3, lines 5-16) but fails to disclose an O-ring.

Vincent et al. teaches and O-ring (71) encircling the distal end of the inner shaft within the trocar cannula (column 4, lines 32-36).

Art Unit: 3731

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an O-ring to the trocar of the combination of Yoon, Riza et al. and Muschler, as taught by Vincent et al., as an additional safeguard for preventing deflation of the cavity during use (column 4, lines 32-36).

- 24. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471) and in view of Muschler (US PGPub No. 2004/0191897A1), as applied to claim 27 above, and further in view of Kellogg (US Patent No. 5,968,060).
- 25. Regarding claim **30**, the combination of Yoon, Riza et al. and Muschler discloses all of the limitations previously discussed except for agitating the trocar.

Kellogg teaches an ultrasonic trocar (10) including a handpiece assembly (50), generator (30), braking mechanism (130) and an acoustic assembly (80) through which ultrasonic energy propagates to cause vibration within the acoustic assembly (column 3, lines 17-20, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the trocar of Yoon, Riza et al. and Muschler with vibrating means, as taught by Kellogg, to create a penetration opening (column 20-30).

Response to Arguments

26. Applicant's arguments with respect to claims 1 and 3-16 citing Yoon, Riza et al. and Jacobson et al. filed 21 December 2009 have been fully considered but they are not persuasive. The Applicant contends that Yoon fails to disclose seals that are

perpendicular to each other and a downflow lumen. However, Riza et al. is used to teach perpendicular seals and Jacobsen is used to teach a downflow lumen (Please see rejection above). In response to applicant's argument that the lumens of Jacobsen are not used to flow fluid through the instrument lumen to remove harmful substances, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the device of Jacobsen is capable of removing any harmful substances from the instrument lumen (25) that may enter through opening (20). The Applicant contends that Jacobsen et al. fails to teach only one opening in the downflow lumen, however, the downflow lumen (12) only has one outlet opening (13) in which the opening opens into the instrument lumen and the fluid exits therefrom (please see rejection above). New rejections to the claims have also been submitted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/ 5/05/2010 Examiner, Art Unit 3731

/Anhtuan T. Nguyen/ Supervisory Patent Examiner, Art Unit 3731 5/7/10